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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/295,691 04/21/99 KAYYEM

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IM62/1215
FLEHR HOHBACH TEST ALBRITTON &
HERBERT L L P
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

EXAMINER

STARSIK, J

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

12/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/291,691	Applicant(s) Jon Fairz Reyem	
Examiner J. STARSIAK	Group Art Unit 1743	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 21 April 1999.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-35 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-35 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5
- ☒ Notice of References Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1743

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cell handling module recited in claims ~~4~~¹ and ~~22~~^{1a}, the cell lysis well recited in claims ~~5~~ and 23, the cell removal well recited in claims ~~6~~ and 24, the cell concentration well recited in claims 7 and ~~25~~, the cell separation well recited in claims ~~8~~ and ~~26~~, the separation module recited in claims 9 and 27, the electrophoresis module recited claims 10 and 28, the reaction module recited in claims 11 and 29, the nucleic acid amplification module in claims 12 and 30, the thermal module recited in claims 13 and 31, the pump recited in claims 14 and 32, the electroosmotic pump recited in claims ~~15~~ and 33, the electrohydrodynamic pump recited in claims ~~16~~ and 33, and the valve recited ~~17~~ and 34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

Art Unit: 1743

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Despite the length of the specification (i.e. 113 pages) the description of the structure is limited (i.e., bulk of the specification is directed to the chemistry of the detector). In the brief description of the drawings the identifies the elements in drawings AD. as sample handling well, storage wells, etc. In the portion of directed to the specification (and claims) the applicant recites a number of other elements such as cell handling modules, sample collection modules, etc. However, the applicant fails to indicate any of the elements in the drawings and fails to recite or illustrate the relationship of the elements to other elements of the invention. M.P.E.P. 608.01 (o) states: "The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure to this import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawings, designating the part or parts therein to which the term applies." In fact the portion of the specification direct to the structure of the device is devoid of any reference to the drawings. Similarly the applicant recites that the invention may contain pumps and valves, but fails to indicate where these elements are located in the device. In addition, the description of each individual element recites little of any structure of the element (mostly description of function and chemistry). It appears the applicant is relying of incorporation of references for most of the structure. In conclusion, the specification recites a catalog of potential elements for the invention without a single complete operative embodiment.

Art Unit: 1743

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are in conflict with each other. In claim 1 recites, "...a solid support comprising...b) a sample handling well....d) a detection module comprising: i)a detection electrode;"....". In claim 2 the applicant recites, "wherein said sample handling well and said detection electrode are *on* the same solid support". How can said sample handling well and said detection electrode be both part of said solid support and on said solid support? In addition, characterizing "a detection module" as part of a "solid support" appears to be repugnant to the normal meaning of a "support", e.g. "One who or that which supports". There is identical language in claims 19 and 20. In claim 3, the applicant recites, "said sample handling well is a reagent storage well. This recitation conflicts with the description of the module. The only discussion of "wells" is in the "brief description of the drawings". In this section the applicant recites a "sample handling well(s)" and "storage wells(s)" which are different elements. Compare this recitation to the recitation in claim 21. In claim 4 the applicant recites, "said sample handling

Art Unit: 1743

well comprises a cell handling module". In claim 9 the applicant recites, "said sample handling well comprises a separation module". In claim 11 the applicant recites, "said sample handling well comprises a reaction module". In claim 13 the applicant recites, "said sample handling well is a thermal module". There are identical recitations in claims 22, 27, 29, and 31, respectively. All of these claims are indefinite because they are repugnant to the normal definition of a "well", i.e. container or reservoir. In other words a "well" is not capable of performing the recited functions of said modules, i.e. additional structure must be recited. The characterization of the well as a "sample handling well" fails to recite any structural limitation. In claim 5 the applicant recites "said cell handling well is a cell lysis well". In claim 6 the applicant recites, "said cell handling well comprises a cell". In claim 7 the applicant recites, "said cell handling well comprises a cell concentration well". In claim 8 the applicant recites, "said cell handling well comprises a cell separation well". There are identical recitations in claims 23, 24, 25, and 26 respectively. These recitations are indefinite for two reasons. One, there is no antecedent basis for "said cell handling well" in claims 4 and 22, respectively. Two, these recitations are repugnant to the normal definition of a "well". See examiner's rejection of claims 4, 9, 11, and 13 above. In claims 14 and 32 the applicant recites, "further comprising a pump". The applicant fails to recite any structural relationship between "the pump" and the elements recited in claims 1 and 19 respectively. In claims 17 and 34 the applicant recites, "further comprising a valve". The applicant fails to recite any structural relationship between "the valve" and any of the elements recited in claim 1 and 19 respectively. Claim 18 is rejected as incomplete because the applicant fails to recite any element

Art Unit: 1743

to create fluid flow through the device, i.e. fluid flow is essential to the operation of the device.

The remaining claims are rejected because they depend on of the above claims.

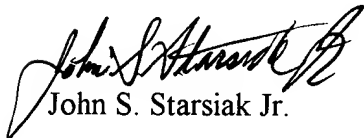
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references cited are the closest references to the present invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Friday from 8:00 AM to 3:30 AM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3559.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


John S. Starsiak Jr.

05 December 2000

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ART UNIT 1743